Attachment I: 510(k) Summary of Safety and Effectiveness

MAY 15 1996

K954980

General Information

Device Generic Name: Cardiograph

Device Trade Name: PageWriter 200i (Model M1770A)
PageWriter 200 (Model M1771A)

Legally marketed predicate device: PageWriter 200i (Model M1770A)
PageWriter 200 (Model M1771A)
PageWriter XLi (Model M1700A)

Applicant:

Hewlett-Packard
Diagnostic Cardiology Division
1700 South Baker Street
McMinnville, Oregon 97128

Indications for Use:

The PageWriter 200 series cardiographs with option #A05 transmit ECGs for management or physician review or copying. ECGs can be transmitted to another PageWriter cardiograph or to a general purpose fax device. Option #A05 also provides ECG storage capability in the cardiograph.

The intended use of the PageWriter 200i and 200 with option #A05 is substantially equivalent to the intended use of the PageWriter XLi with Direct Digital FAX (Model M1706B) currently marketed which received FDA's substantial equivalence determination under K#941282, i.e., **it is intended to be used to transmit ECGs for management or physician review or copying and transmit to another device**.

The PageWriter 200i and 200 with option #A05 is intended to be used in a hospital environment or in a physician's office. The cardiograph is used to acquire, digitize, record, and transmit conventional diagnostic 12 simultaneous lead ECG waveforms and ECG data. The cardiograph also records patient data entered through the alphanumeric keyboard. Additionally, the PageWriter 200i cardiograph measures and provides ECG interpretation. The interpreted ECG with measurements and diagnostic statements is offered to the physician on an advisory basis only, and the physician is asked to overread and validate (or change) the ECG interpretation.

Device Description:

PageWriter 200 series cardiographs with option A05 will:
- Transmit via direct connect or fax modem using a Hewlett Packard digital communications protocol to PageWriter XLi cardiographs (Model M1700A, K#895520) and PageWriter 200 series cardiographs with A05
- Transmit to and receive from an automated HP ECG management system.
- Transmit to CCITT group III fax machines.
- Store up to 30 AUTO ECGs in solid state memory for later retrieval or transmission.

PageWriter 200 series cardiographs with option A05 will NOT:
- Receive fax from CCITT group III fax machines.

Option A05 adds a new printed circuit board to the predicate device hardware. The new printed circuit board interfaces to the predicate hardware via an existing connector located on the main control board. The existing connector is used during production to interface with our manufacturing test system.

Option A05 does not include the fax modem device. The fax modem device may be ordered using Model number M1706B or the customer may purchase an equivalent fax modem device. A modem is connected to the cardiograph via the RS 232 connector on the rear of the cardiograph. The modem derives power from AC line power. The modem is connected to the phone line via a cable. The modem is a standard general purpose modem. Software is added to the cardiograph to enable the cardiograph to recognize the modem.

The predicate device is the PageWriter XLi cardiograph with the M1706B Direct Digital ECG Fax modem. The predicate device was cleared for market by the FDA in 1995.

Marketing History

The PageWriter 200 series cardiographs with option A05 are not currently sold in the U.S. or foreign markets.

Adverse Effects of the Device on Health

The level of concern is minor regarding direct risks to the patient. In many years of experience, there has been no reported instance of a patient suffering acute adverse effects, much less death, irreversible illness or permanent injury, as a consequence of the use of an electrocardiograph, provided of course that the device meets generally accepted standards for electrical safety (patient risk currents). There is no known case of software failure which would result in direct injury or death to the patient. Clearly, the risk of not using the cardiograph is the lack of diagnostic information which may affect the physician's assessment of the patient and treatment decisions.

The M1770A produces a suggested ECG interpretation based on computerized measurement and analysis of the ECG. However, this information is only advisory and it is specifically recommended that a qualified physician overread the ECG and make a final interpretation before formulating a diagnosis. The physician analyzes the 12 lead produced by cardiograph and then makes a diagnosis and other decisions based on all information available, not limited to the ECG.

If the cardiograph should produce a grossly distorted or inaccurate ECG it would be recognized as corrupted data. The clinician has the printed trace, the patient history, the patient condition, and knowledge of the morphology of arrhythmia and other disturbances.. If the ECG trace did not correlate to other known data the clinician would suspect the data and rerun the test prior to administering any therapy.

If the cardiograph were to provide slightly distorted data both the probability and the implications of misdiagnosis and resultant mistreatment would be accordingly minor.

The modified device produces the same informatior and data as the predicate device.

In summary, the software does not directly control the delivery of any energy into the patient. The cardiograph provides data for diagnosis within the control and review of competent human intervention (i.e. a nurse or physician). The information provided by the cardiograph is always subject to medical judgment and supplements data available from other independent clinical sources. The software does not control any system that could threaten a patient's life or well-being in any way and has been analyzed to ensure product safety and effectiveness.

On the basis of the above consideration, a "minor" level of concern seems appropriate. Death or serious injury is not possible as a direct result of the use of the cardiograph with optional storage and transmission capability, and an incorrect diagnosis caused by faulty operation of the cardiograph will not occur when appropriate standards are met.